



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/599,926

06/18/2007

Felicia A. Etzkorn

01640460AA

6640

30743

7590

12/18/2009

WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

12/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,926	Applicant(s) ETZKORN ET AL.	
	Examiner MAURY AUDET	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

PRODUCTS I & II

- I. Claims 1-15, 18 and 25, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(1A): (Gly-Psi[(E)CH=C]-Xaa-Yaa)_n** (e.g. **claim 25 (Gly-Psi[(E)CH=C]-Pro-Pro)_n**.
- II. Claims 1-2, 4-15, and 18 drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(1B): (Gly-Xaa-Psi[(E)CH=C]-Yaa)_n**.
- III. Claims 1-2, 4-15, and 18, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(1C): (Gly-Xaa-Yaa-Psi[(E)CH=CH])_n**.
- IV. Claims 1-2, 4-15, and 18, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(2A): (Gly-Psi[(E)CH=C]-Yaa-Psi[(E)CH=C]-Yaa)_n**.
- V. Claims 1-2, 4-15, and 18, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(2B): (Gly-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

Art Unit: 1654

VI. Claims 1-2, 4-15, and 18, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(2C): (Gly-Psi[(E)CH=C]-Xaa-Yaa-Psi[(E)CH=CH])_n**.

VII. Claims 1-2, 4-15, and 18, drawn to a polymeric material or biocompatible adhesive comprising the tripeptide peptidomimetic of **(3): (Gly-Psi[(E)CH=C]-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

METHOD I-Tissue Replacement

VIII. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1A): (Gly-Psi[(E)CH=C]-Xaa-Yaa)_n** (e.g. **claim 25 (Gly-Psi[(E)CH=C]-Pro-Pro)_nPro-Pro)_n**.

IX. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1B): (Gly-Xaa-Psi[(E)CH=C]-Yaa)_n**.

X. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1C): (Gly-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XI. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(2A): (Gly-Psi[(E)CH=C]-Yaa-Psi[(E)CH=C]-Yaa)_n**.

XII. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(2B): (Gly-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

XIII. Claim 16, drawn to a method of tissue replacement using a polymeric material

Art Unit: 1654

comprising the tripeptide peptidomimetic of **(2C): (Gly-Psi[(E)CH=C]-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XIV. Claim 16, drawn to a method of tissue replacement using a polymeric material comprising the tripeptide peptidomimetic of **(3): (Gly-Psi[(E)CH=C]-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

METHOD II-Hip Replacement

XV. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1A): (Gly-Psi[(E)CH=C]-Xaa-Yaa)_n** (e.g. claim 25 **(Gly-Psi[(E)CH=C]-Pro-Pro)_nPro-Pro)_n**.

XVI. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1B): (Gly-Xaa-Psi[(E)CH=C]-Yaa)_n**.

XVII. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(1C): (Gly-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XVIII. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(2A): (Gly-Psi[(E)CH=C]-Yaa-Psi[(E)CH=C]-Yaa)_n**.

XIX. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(2B): (Gly-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

XX. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(2C): (Gly-Psi[(E)CH=C]-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XXI. Claim 17, drawn to a method of hip replacement using a polymeric material comprising the tripeptide peptidomimetic of **(3): (Gly-Psi[(E)CH=C]-Xaa-Psi[(E)CH=C]-Yaa-**

Art Unit: 1654

Psi[(E)CH=CH]n.**METHOD III-Biomineralization**

XXII. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(1A): (Gly-Psi[(E)CH=C]-Xaa-Yaa)n** (e.g. **claim 25 (Gly-Psi[(E)CH=C]-Pro-Pro)nPro-Pro)n**.

XXIII. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(1B): (Gly-Xaa-Psi[(E)CH=C]-Yaa)n**.

XXIV. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(1C): (Gly-Xaa-Yaa-Psi[(E)CH=CH])n**.

XXV. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(2A): (Gly-Psi[(E)CH=C]-Yaa-Psi[(E)CH=C]-Yaa)n**.

XXVI. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(2B): (Gly-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])n**.

XXVII. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(2C): (Gly-Psi[(E)CH=C]-Xaa-Yaa-Psi[(E)CH=CH])n**.

XXVIII. Claim 19, drawn to a method of biomineralization using a polymeric material comprising the tripeptide peptidomimetic of **(3): (Gly-Psi[(E)CH=C]-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])n**.

Art Unit: 1654

METHOD IV-Drug Delivery

XXIX. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(1A): (Gly-Psi[(E)CH=C]-Xaa-Yaa)_n** (e.g. **claim 25 (Gly-Psi[(E)CH=C]-Pro-Pro)_nPro-Pro)_n**.

XXX. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(1B): (Gly-Xaa-Psi[(E)CH=C]-Yaa)_n**.

XXXI. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(1C): (Gly-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XXXII. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(2A): (Gly-Psi[(E)CH=C]-Yaa-Psi[(E)CH=C]-Yaa)_n**.

XXXIII. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(2B): (Gly-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

XXXIV. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(2C): (Gly-Psi[(E)CH=C]-Xaa-Yaa-Psi[(E)CH=CH])_n**.

XXXV. Claim 20, drawn to a method of drug delivery using a polymeric material comprising the tripeptide peptidomimetic of **(3): (Gly-Psi[(E)CH=C]-Xaa-Psi[(E)CH=C]-Yaa-Psi[(E)CH=CH])_n**.

METHOD V-Synthesizing Collagen-Like Peptide

XXXVI. Claims 21-24, drawn to a method of synthesizing collagen-like peptide comprising polymerization of the tripeptide peptidomimetic monomer of **H-Gly-Psi[(E)CH=C]-Pro-Hyp-OH**.

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

No 'Special' Technical Feature

The only fixed core 'technical feature' found to be running through the 8 expressly claimed tripeptide peptidomimetics found in claims 1 and 25, is that of – Psi[(E)CH=C – which Applicant Wang already taught in an earlier publication, antedating the present application, on page 2346, bottom of first column before "Conclusion" section [Note (E) = E/Z stereochemistry nomenclature of alkenes]:

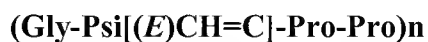
Wang et al.; Serine-cis-proline and serine-trans-proline isosteres: stereoselective synthesis of (Z)- and (E)-alkene mimics by Still-Wittig and Ireland-Claisen rearrangements; J. Org Chem 2003 March 21; 68(6) 2343-2349. [1 of present Inventors; Cited in IDS of 7/17/07 & Cited by Former Examiner Shirali in r/t PCT/US05/12409 Form 210 Search Report].

Art Unit: 1654

Thus, the technical feature is known in the art. Therefore it does not constitute a ‘special’ technical feature, and the claims lack unity of invention.

Requirement for Election of a Single (1 of 8) Fully Defined Peptidomimetic as the Invention

As described above, core of the tripeptide peptidomimetics found in claims 1 and 25, is that of – Psi[(E)CH=C – which Applicant Wang already taught in an earlier publication, was known in the art. Each tripeptide peptidomimetic, other than Gly, may contain ANY amino acid at either of the other 2 peptide positions. Each tripeptide peptidomimetic constitutes a distinct peptide. Which requires an individual sequence and/or structure search of each tripeptide peptidomimetic and its modifications, as there is no overlapping coextensive search possible. The search of each and every tripeptide peptidomimetic and its modifications would thus constitute an undue search burden. **Therefore, if any of Groups I - XXXV is elected as the invention, Applicant must elect a single tripeptide peptidomimetic as the invention (not species), to which the elected Invention group will be searched, e.g.: see claim 25, depending from claim 1:**



This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Art Unit: 1654

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1654

Claim Observation

In claim 1, the phrase "n means an integer" is asked to be clarified either in response hereto or by amendment (e.g. an integer of 1-5?). Under the broadest reasonable interpretation of integer, it is arguably indefinite as to what is meant by this term.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/16/2009

/Maury Audet/
Examiner, Art Unit 1654
Full Sign. Auth. Program